## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NORTH CAROLINA WESTERN DIVISION No. 5:20-CV-162-D

CATHY HILL, Plaintiff,	)
<b>v.</b>	ORDER
BIOMET, INC.; BIOMET, INC. dba ZIMMER BIOMET; ZIMMER BIOMET HOLDINGS, INC.; ZIMMER BIOMET HOLDINGS, INC. dba ZIMMER BIOMET; ZIMMER, INC.; ZIMMER, INC. dba ZIMMER BIOMET; ZIMMER US, INC., BIOMET ORTHOPEDICS, LLC; BIOMET U.S. RECONSTRUCTION, LLC; BIOMET MANUFACTURING, LLC; and DOES 1–20, Inclusive,	
Defendants.	, )

On April 17, 2020, Cathy Hill ("Hill" or "plaintiff") filed a complaint against Biomet, Inc.; Biomet, Inc. doing business as Zimmer Biomet; Zimmer Biomet Holdings, Inc.; Zimmer Biomet Holdings, Inc. doing business as Zimmer Biomet; Zimmer, Inc. doing business as Zimmer Biomet; Zimmer Biomet US, Inc.; Biomet Orthopedics, LLC; Biomet U.S. Reconstruction, LLC; Biomet Manufacturing, LLC (collectively "Biomet," "Biomet defendants," or "defendants") for North Carolina law claims related to an allegedly defective medical device [D.E. 1]. On October 19, 2020, the court entered a scheduling order setting May 7, 2021, as the deadline for expert reports [D.E. 19]. Hill did not submit any expert reports. On May 17, 2021, Biomet moved for summary judgment [D.E. 27] and filed documents in support [D.E. 28–30]. On June 28, 2021, Hill responded in opposition [D.E. 36–38]. On June 29, 2021, Hill moved for the court to take judicial notice of certain public records related to Biomet products [D.E. 39]. On August 2, 2021, Biomet replied [D.E. 41, 43, 44], and responded opposing Hill's motion for judicial notice [D.E. 42]. As explained

below, the court grants Biomet's motion for summary judgment and denies as moot Hill's motion to take judicial notice.

I.

In 2012, Hill, a North Carolina citizen, underwent a total right hip replacement. See Compl. [D.E. 1] ¶¶ 1, 15. The Biomet defendants are Indiana and Delaware corporations, and Hill alleges that her implant was a "Biomet orthopedic [i]mplant with ring lock plus Acetabular Shell." Id. ¶ 15; [D.E. 14] ¶¶ 3–11. Hill claims that she subsequently had numerous revision surgeries and that during one of those procedures, doctors discovered that a flange from the acetabular cup cage in her orthopedic implant broke and was "free floating" in her leg. Compl. ¶¶ 16–25. Hill alleges that the acetabular cup was defective. See id. ¶ 26.

The court exercises diversity jurisdiction, and the parties agree that North Carolina substantive law applies. In applying North Carolina substantive law, the court "must determine how the Supreme Court of [North] Carolina would rule." Twin City Fire Ins. Co. v. Ben Arnold-Sunbelt Beverage Co. of S.C., 433 F.3d 365, 369 (4th Cir. 2005). In doing so, the court must look first to opinions of the Supreme Court of North Carolina. See id.; Parkway 1046, LLC v. U.S. Home Corp., 961 F.3d 301, 306 (4th Cir. 2020); Stahle v. CTS Corp., 817 F.3d 96, 100 (4th Cir. 2016). If there are no governing opinions from the Supreme Court of North Carolina, this court may consider the opinions of the North Carolina Court of Appeals, treatises, and "the practices of other states." Twin City Fire Ins. Co., 433 F.3d at 369 (quotation omitted).

Summary judgment is appropriate when, after reviewing the record taken as a whole, no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. See Fed. R. Civ. P. 56(a); Scott v. Harris, 550 U.S. 372, 378 (2007); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247–48 (1986). The party seeking summary judgment must initially demonstrate

<sup>&</sup>lt;sup>1</sup> North Carolina has no mechanism for certifying questions of state law to the Supreme Court of North Carolina. See Town of Nags Head v. Toloczko, 728 F.3d 391, 398 (4th Cir. 2013).

the absence of a genuine issue of material fact or the absence of evidence to support the nonmoving party's case. See Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986). Once the moving party has met its burden, the nonmoving party may not rest on the allegations or denials in its pleading, see Anderson, 477 U.S. at 248–49, but "must come forward with specific facts showing that there is a genuine issue for trial." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986) (emphasis and quotation omitted). "[T]here is no issue for trial unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party." Anderson, 477 U.S. at 249. "The mere existence of a scintilla of evidence" is insufficient; "there must be evidence on which the [factfinder] could reasonably find for the" nonmoving party. Id. at 252.

In making this determination, the court must view the evidence and the inferences drawn therefrom in the light most favorable to the nonmoving party. See Scott, 550 U.S. at 378. Nevertheless, the court is not "required to submit a question to a jury merely because some evidence has been introduced by the party having the burden of proof, unless the evidence be of such a character that it would warrant the jury in finding a verdict in favor of that party." Anderson, 477 U.S. at 251 (quotation omitted). "[C]onclusory statements, without specific evidentiary support," do not create genuine issues of material fact. Causey v. Balog, 162 F.3d 795, 802 (4th Cir. 1998). Only factual disputes that affect the outcome of the case properly preclude summary judgment. See Anderson, 477 U.S. at 247–48.

Π.

Hill asserts five North Carolina law claims, including negligence, negligent breach of implied warranty, intentional breach of implied warranty, willful and intentional breach of duty to warn, and negligent breach of duty to warn, all based out of the allegedly defective acetabular shell in her orthopedic implant. See Compl. ¶¶ 31–76. Each of these claims requires Hill to prove causation.

"A products liability claim normally contemplates injury or damage <u>caused</u> by a defective product... and recovery is premised on either negligence or on the contract principles of warranty."

Red Hill Hosiery Mill, Inc. v. Magne Tek, Inc., 138 N.C. App. 70, 74–75, 530 S.E.2d 321, 325–26 (2000) (emphasis added; quotation omitted); see Moore v. Coachmen Indus., Inc., 129 N.C. App. 389, 397, 499 S.E.2d 772, 777 (1998); Crews v. W.A. Brown & Son, Inc., 106 N.C. App. 324, 328–29, 416 S.E.2d 924, 928 (1992). "Under North Carolina law, which the parties agree applies to the claims before us, a plaintiff bringing a products liability action based on negligence must prove (1) the product was defective at the time it left the control of the defendant, (2) the defect was the result of defendant's negligence, and (3) the defect proximately caused plaintiff damage." Farrar & Farrar Farms v. Miller-St.Nazianz, Inc., 477 F. App'x 981, 984 (4th Cir. 2012) (per curiam) (unpublished) (emphasis added; quotation omitted); see Red Hill Hosiery Mill, 138 N.C. App. at 75, 530 S.E.2d at 326; cf. Holley v. Burroughs Wellcome Co., 318 N.C. 352, 355, 348 S.E.2d 772, 774 (1986).

"In North Carolina, a failure to warn claim requires the plaintiff to prove that the defendant unreasonably failed to provide an adequate warning, such failure was the proximate cause of the plaintiff's damages, and the product posed a substantial risk of harm without an adequate warning either at the time of or after leaving the manufacturer's control." Carlson v. Bos. Sci. Corp., 856 F.3d 320, 324 (4th Cir. 2017) (emphasis added; quotation omitted); see N.C. Gen. Stat. § 99B-5(a); Evans v. Evans, 153 N.C. App. 54, 57–58, 569 S.E.2d 303, 308 (2002); see also Teague v. Johnson & Johnson, Inc., No. 5:21-CV-68-FL, 2022 WL 56526, at \*5 (E.D.N.C. Jan. 5, 2022).

Finally, under North Carolina law, a plaintiff basing a products liability action on a breach of an implied warranty of merchantability must prove: "(1) that the goods bought and sold were subject to an implied warranty of merchantability; (2) that the goods did not comply with the warranty in that the goods were defective at the time of sale; (3) that his <u>injury was due to the defective nature of the goods</u>; and (4) that damages were suffered as a result." <u>DeWitt v. Eveready Battery Co., Inc.</u>, 355 N.C. 672, 683, 565 S.E.2d 140, 147 (2002) (emphasis added; quotations omitted); <u>see Morrison v. Sears, Roebuck & Co.</u>, 319 N.C. 298, 301, 354 S.E.2d 495, 497 (1987).

Hill's claims require Hill to prove causation between the alleged product defect and her injury. To prove that a defect in a medical device directly or proximately caused injury usually requires expert medical evidence to establish the causal relationship. See Click v. Pilot Freight Carriers, Inc., 300 N.C. 164, 167, 265 S.E.2d 389, 391 (1980) (discussing the necessary proof of medical causation in the worker's compensation context, which also requires showing proximate cause); see also Hensley v. Danek Med., Inc., 32 F. Supp. 2d 345, 350 (W.D.N.C. 1998) ("In North Carolina, a jury award cannot be sustained in the absence of expert medical testimony on the issue of causation."); Hassell v. Onslow Cnty. Bd. of Educ., 362 N.C. 299, 308, 661 S.E.2d 709, 715 (2008); Thacker v. City of Winston-Salem, 125 N.C. App. 671, 676, 482 S.E.2d 20, 23 (1997) ("[T]he record is devoid of any medical evidence to establish the necessary causal relationship without conjecture and remote possibility.").

Biomet argues that Hill cannot establish causation because she does not have an expert medical witness or expert medical evidence. See [D.E. 30] 4–8. Hill responds that North Carolina law does not require such expert medical evidence. See Resp. [D.E. 36] 6–8. Rather, Hill argues that medical evidence to show causation need not be in the form of expert testimony. See id. Hill also claims that she "identified her orthopedic surgeon Dr. Samuel Wellman as an expert witness by identifying him in Plaintiff's Initial Disclosures." Id. at 5. Biomet replies that Hill failed to file either a report from Dr. Wellman or a disclosure of the subject matter and a summary of the facts and opinions on which Dr. Wellman is expected to testify and thereby violated both Federal Rule of Civil Procedure 26(a)(2) and this court's scheduling order. See Fed. R. Civ. P. 26(a)(2)(A)–(B); [D.E. 19]; [D.E. 41] 4–5.

Even if the court ignored Hill's glaring procedural failures, allowed Dr. Wellman to testify as a medical expert, and considered Hill's initial disclosures and Dr. Wellman's notes in the medical records as a summary of his testimony, Dr. Wellman's testimony does not create a genuine issue of material fact about causation. Dr. Wellman's treatment notes state that "Hill has had progressive

sensory loss and plantarflexion weakness of her right lower extremity. This started after it was noted that the ischial flange of her cup-cage construct had broken and moved." [D.E. 38-2] 38; see Resp. at 7. Dr. Wellman's statement, however, does not show causation. See Singletary v. N.C. Baptist Hosp., 174 N.C. App. 147, 154, 619 S.E.2d 888, 893 (2005) ("[I]f an expert's opinion as to causation is wholly premised on the notion of post hoc ergo propter hoc (after it, therefore because of it), then the expert has not provided competent record evidence of causation.").

Assuming without deciding that Hill could rely on medical evidence other than expert testimony from Dr. Wellman to prove causation, Hill's other evidence does not create a genuine issue of material fact as to causation. For medical evidence, Hill offers her medical records. See [D.E. 38-2]. As discussed, these medical records do not provide evidence of causation. Hill also offers evidence of FDA and other documents related to Biomet products, other than the one implanted in Hill, that she seeks to introduce through her motion for judicial notice. See [D.E. 39, 39-2, 39-3, 39-4]. Assuming without deciding that the court should take judicial notice of this evidence, the records do not create a genuine issue of material fact because they do not involve the product that Hill alleges was defective. See id.

Next, Hill suggests that she can rely on a res ipsa loquitur inference to establish causation. See Resp. at 8–9. However, in a product-defect case, the plaintiff must establish the specific product defect at issue caused the plaintiff's injuries. See Brittain v. Motorola Mobility, LLC, No. 5:17-CV-00134-KDB-DSC, 2019 WL 3543688, at \*5–6 (W.D.N.C. Aug. 2, 2019) (unpublished) ("To survive summary judgment on a products-liability claim under Chapter 99B–1.1 of the North Carolina General Statutes . . . . a plaintiff is obligated to come forward with expert medical opinion that his medical problems were caused by the defective product."); Sparks v. Oxy-Health, LLC, 134 F. Supp. 3d 961, 991 (E.D.N.C. 2015) (concluding that even if res ipsa loquitur could be used to infer negligence in a products liability action, a plaintiff still "must demonstrate a causal connection between the product itself and the harm suffered"). Moreover, res ipsa loquitur applies when the

defendant had exclusive control over the thing causing harm. See Sparks, 134 F. Supp. 2d at 991. Here, both Biomet and the doctors operating on Hill had control of the acetabular cup before it was implanted in Hill's leg. See Compl. ¶¶ 15–21, 24–25.

In opposition, Hill cites <u>Click v. Pilot Freight Carriers, Inc.</u> and contends that the court can infer causation. <u>See</u> 300 N.C. at 167, 265 S.E.2d at 391; Resp. at 8. In <u>Click</u>, however, medical expert testimony was necessary to prove causation. <u>See Click</u>, 300 N.C. at 168–69, 265 S.E.2d at 391 ("[W]here the exact nature and probable genesis of a particular type of injury involves complicated medical questions far removed from the ordinary experience and knowledge of laymen, only an expert can give competent opinion evidence as to the cause of the injury."). Moreover, although the <u>Click</u> court posited in dicta that some case may exist where an injury's cause was so obvious that expert testimony would not be required, this is not such a case. Here, Hill alleges that after multiple surgical procedures for hip replacement and revision, she suffered "unexplained progressive sensory loss and plantarflexion weakness in her right lower extremity." Compl. ¶ 23; Pl.'s 56.1 Statement [D.E. 37] ¶ 11. Thus, this case requires expert medical evidence to demonstrate causation. Hill has not produced expert medical evidence of causation sufficient to survive summary judgment, and res ipsa loquitur does not save her claims.

Even viewing the evidence in the light most favorable to Hill, no rational jury could find causation on any of Hill's claims based on the evidence in the record. Therefore, the court grants defendants' motion for summary judgment.

Ш.

In sum, the court GRANTS defendants' motion for summary judgment [D.E. 27] and DENIES as most plaintiff's motion for judicial notice [D.E. 39]. Defendants may apply for costs in accordance with the Federal Rules of Civil Procedure and this court's local rules.

SO ORDERED. This 9 day of March, 2022.

JAMES C. DEVER III

United States District Judge